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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,934	12/31/2003	Thomas E. Tarara	0101.00	1899

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NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
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EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
11/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/750,934	**Applicant(s)** TARARA ET AL.	
	Examiner Leah Schlientz	**Art Unit** 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 November 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *38,39,41,42,44,47-58,60,62-68 and 103-105*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet..
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claims 104 and 105 under 35 112, second paragraph, has been withdrawn as being overcome by amendment.

Continuation of 11. Claims 38, 39, 41, 42, 47, 52 are provisionally rejected on the grounds of obviousness-type double patenting for reasons set forth in the previous Office Action.

Claims 38, 39, 41, 42, 47-58, 60, 62-68 and 103-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers et al. (WO 01/85136, whereby US 2002/0037316 is relied upon as equivalent), for reasons set forth in the previous Office Action.

Applicant argues that the Examiner has relied upon a single reference as the basis for rejecting Applicants' claims under 103(a), and that the Examienr has not submitted an affadavit to make facts of record in the prosecution, and that the Examiner provides only an opinion.

This is not found to be persuasive. The Weers document teaches budesonide and amphotericin. The solubility of budesonide and amphotericin is an inherent feature of the drugs. A compound and its properties are inseparable. Since Weers teaches amphotericin, as claimed by Applicant, the same drugs would inherently have the same solubility as that which is claimed. With regard to the limitation that the active agent particles have a low Tg, the formulations of Weers would also inherently meet this limitation because Weers teaches the same actives as those which are now claimed (e.g. amphotericin). Thus, the same active agent particles would inherently have the same Tg as that which is now claimed. This interpretation is supported by Applicants own specification, which recites that active agents have an inherent Tg (see published paragraph 0007 of specification). Accordingly, solubility and glass transition temperature have been propertly established as inherent properties of a drug, and an affadavit is not required to provide such facts.

Applicant further argues that while Weers mentions the possibility of formulating insoluble active agents, does not provide any teaching or guidance as to how to do so (apart from suggesting they be dispersed in an emulsion, and that Weers does not teach a particulate engineered for pulmonary administration wherein the particulate comprises an insoluble particle having a geometric diameter of less than about 3 microns and dispersed within a phospholipid matrix. Applicant asserts that Weers can not teach or suggest such a claim limitation as Weers does not relate to incorporation of discrete insoluble particles in a matrix.

This is not found to be persuasive. Weers clearly teaches how to make a suitable formulation of at least one insoluble active, e.g. see Example V. Such an example clearly teaches a phospholipid matrix, not merely discrete particles.

Applicant argues that Weers does refer in Example V to powders which incorporate poorly soluble actives, but does not specifically teach or suggest the claimed compositions, and methods of making, comprising porous particulates consisting essentially of active agent particles in a matrix comprising a phospholipid, the active agent particles having a geometric diameter of less than about 3 micron and a solubility in water of about 0.1 to about 1 mg/ml and wherein the active agent particles are dispersed within the phospholipid matrix. Applicant asserts that the example incorporates an excipient (lactose monohydrate) thus teaching the opposite of the invention claimed.

This is not found to be persuasive. With regard to the presence of lactose excipient in the particle in the cited example, it is noted that that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003). In the instant case, there is no definition in the specification as originally filed that “consisting essentially of” language should preclude the presence of additional components and what characteristics they would have, therefore, the claim has been construed as equivalent to “comprising” language.